

REMARKS

Claims 1, 15, 18, 22, 25 and 29 are amended. Claims 2, 21, 23 and 27 are cancelled. New claim 30 is added. Upon entry of this amendment, claims 1, 3-20, 22-26 and 28-30 will be pending.

Background

Full length and knee length compression sleeves for use in vascular therapy have been sold separately for many years. Two of the references cited by the examiner show such sleeves. Dye U.S. Patent No. 5,795,312, owned by applicant, discloses a full-length sleeve sized to cover the calf, knee and thigh. Rotta U.S. Patent No. 3,862,629 discloses a knee-length sleeve sized to cover just the calf. The benefits of the present invention include greater comfort for the patient and reduced cost to the hospital. For example, a patient may be prescribed a mixed vascular therapy starting with the use of a full-length compression sleeve, followed by a period of time using a knee-length sleeve. With the tear away perforations of the present invention, there is no need for the hospital to replace the full-length sleeve with a new knee-length sleeve. The patient can use the same sleeve (with the thigh portion removed) to complete the prescribed vascular therapy. This reduces cost because the hospital does not throw away the single patient use thigh length device. Removal of a portion of the sleeve also increases the comfort and mobility of the patient. This helps with patient compliance because the patient can remove the uncomfortable thigh portion in favor of the sleeve below the knee.

Claim Amendments

Independent claims 1, 15, 22 and 29 are amended to emphasize that the apparatus of this invention is directed to apparatus for carrying out vascular therapy on a patient, that is, a therapy for increasing the blood circulation of a patient to avoid medical conditions that form clots in the blood, such as deep vein thrombosis and peripheral edema. All of these claims are further amended to state that a compression apparatus of this invention comprises a sleeve having perforations which extend continuously across

the sleeve from adjacent one boundary edge of the sleeve to adjacent an opposite boundary edge of the sleeve so that a first portion of the sleeve (e.g., a thigh portion) may be torn completely from a second portion of the sleeve (e.g., the calf portion). Thus, the perforations provide for a quick and easy way to shorten the length of the sleeve which has the benefits described earlier.

Claim 29 is further amended to state that the connector for fluidly connecting the pressurized fluid source to the inflatable chambers of the sleeve comprises a valve which operates to partially close a fluid port in the connector when the first tubing is removed from the connector. As a result, fluid continues to flow from the fluid port of the connector after the first portion of the sleeve and the first tubing supplying pressurized fluid to it are removed. This continued flow is important for reasons which will be explained later.

Independent claims 18 and 25 are directed to a method of this invention in which a compression sleeve is inflated and deflated to carry out vascular therapy. These claims have been amended to emphasize that the sleeve is torn along the perforations in a way which **completely** remove a first portion of the sleeve (e.g., a thigh portion) from a second portion of the sleeve (e.g., the calf portion). Again, the perforations provide for a quick and easy way to shorten the length of the sleeve which has the benefits described earlier.

Claim Rejections - 35 USC §103

Claims 1, 5-7, 11, 13, 14, and 18-20 have been rejected as being unpatentable over Oguri et al. (5,938,628) in view of Islava (6,719,711) and Poole et al. (4,624,248). Applicant disagrees.

The Oguri et al. patent is directed to a suit-type cosmetic air massage device having an upper suit-shaped part 11 containing a first set of air bags for massaging the upper torso and arms of a user and a lower suit-shaped part 12 containing a second set of air bags for massaging the lower torso and legs of the user. The air hoses 14 for inflating the first set of air bags are connected to the air hoses 14 for inflating the second set of air bags by two connectors 151. The air hoses 14 in the legs of the suit are connected to air hoses 14 from the intake/exhaust instrument 13 by two additional connectors 152. Each

of the connectors 151, 152 comprises upper and lower members (151U, 151L, 152U, 152L) which "can easily be separated/connected by operating hooks (not shown)" (column 5, lines 29-31; column 6, lines 5-7). By disconnecting the connectors 151, 152, the suit-type device can be divided up into three parts, i.e., the upper part 11, the lower part 12 and the intake/exhaust instrument 13. As a result, a user can use the upper and lower parts 11, 12 together (Fig. 4), or the upper part without the lower part (Fig. 5) or the lower part without the upper part (Fig. 6).

Clearly, there is no disclosure in Oguri et al. of providing perforations along which a sleeve may be torn to completely remove a first portion of the sleeve from a second portion of the sleeve as stated in amended claim 1. On the contrary, the upper and lower parts of the suit in Oguri et al. are separate from one another except for the hose connectors 151, and one part of the suit is removed from the other part by disconnecting the upper and lower members of the connectors. No tearing along perforations is involved. Further, the connectors 151 allow the various parts of the suit to be re-connected to one another. The re-usable nature of the connection is fundamentally different from applicant's claimed design where the perforations allow only for a complete and irreversible removal of one part of the sleeve from another part of the sleeve. Once the parts are torn apart, they cannot be re-connected.

The Islava patent is directed to an inflatable splint which is used to immobilize a broken limb such as an arm. The Islava device has two or more rows of latitudinal air chambers 22 which are inflated by conventional blow spout 18. The rows of chambers are separated by perforated welds 40, 42 along which the splint may be torn. In the preferred embodiment (e.g., Figs. 1a and 1b), the perforated weld extends only partially across the splint, thereby leaving a central area 29 intact to function as a hinge after the splint is partially torn. Islava teaches away by making no suggestion to completely remove the inflatable portions in use. It is not obvious to modify Islava to be a tear away device because any such modification would render the Islava device *unsuited for its intended purpose* of maintaining a hinge on which the various portions of the splint can be manipulated to support a broken limb. Islava explicitly teaches away from tearing completely along its perforations to separate the portions of the inflatable splint.

Contrary to the assertions made in the Office action, the skilled person would not have found it obvious to detachably connect the various sections of the massage suit of Oguri et al. by using perforations as shown in Islava. Oguri et al. requires connectors that can be re-connected so the various parts of the suit can be rearranged and reused. Perforations, once torn, cannot be reconnected. The examiner states that the use of perforations would provide more structural support between the sections of Oguri et al. But exactly how would that support be provided? Would this additional "structural support" be provided by **replacing** the connectors 151 with perforations or would such support be provided by using perforations **in combination with** the connectors 151? Clearly, the perforations could not be used as a substitute for the connectors 151, because the parts could not be re-connected after the perforations are torn to remove one part from the other. Nor is it apparent how the perforations could be used in combination with the connectors 151, because the connectors would actually prevent a line of perforations from extending completely across the juncture between the two parts. Moreover, in a device like Oguri et al. where the parts are clearly intended to be disconnected and then re-connected, the perforations would serve no purpose after the sections are detached and then re-connected. Thus, there would be little incentive or advantage to connecting the sections in the first place, and the skilled person would not do so.

Further, as amended, claim 1 states that the perforations extend continuously across the sleeve from adjacent one boundary edge of the sleeve to adjacent an opposite boundary edge of the sleeve to allow a first part of the sleeve to be **completely** removed from a second part of the sleeve. The entire emphasis in Islava is toward only **partially** tearing the splint along the perforated weld 40, 42. In this way, the center portion 29 of the splint remains intact so that it can function as a hinge. See for example column 4, lines 1-5, stating that in the preferred embodiment, the latitudinal welds do not extend across the entire width of the splint so that a center portion of the splint remains undivided; column 4, lines 53-61, stating that the center portion shown in Fig. 1a serves as a flexure upon which the two portions 50, 60 bend toward or away from one another; and column 6, lines 27-29, stating that the center portions shown in Fig. 6 serve to couple the rows of air chambers together and thus keep the splint as "one integral piece." Clearly, therefore, unlike applicant's claimed invention which involves tearing to effect

the **complete** removal of a portion of the sleeve, the express purpose of Islava's perforation is to allow only a **partial** detachment of the two sections so that each section can be bent into a U-shape independent of the other section while remaining connected by the hinge (29). See column 4, lines 53-61. There is no need for a hinge to allow any such bending in the massage device of Oguri et al. On the contrary, maintaining a hinged connection between two parts of the suit would interfere with the disconnection and re-attachment of the parts and render the modified device inoperable for its intended purpose. (See MPEP 2143.01(V) stating that "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.") For this additional reason, the skilled person would not modify Oguri et al. in view of Islava in the manner suggested by the examiner.

Still further, it is submitted that Islava fails to teach applicant's claimed construction wherein the perforations extend **continuously** across the sleeve from adjacent one boundary edge of the sleeve to adjacent an opposite boundary edge of the sleeve, the sleeve is torn along the perforations to completely remove a first portion of the sleeve from a second portion of the sleeve. In this regard, the skilled person would recognize that if Islava's perforated weld 40 were extended to run continuously across the splint from one side of the splint to an opposite side of the splint, the splint could not be properly inflated in the first place because the weld 40 would block the flow of air into the air chambers located on the side of the weld opposite the blow spout 18. Alternatively, if an air passage was provided across the weld to allow inflation of all air chambers, then tearing along the perforations would breach the passage and the entire splint would deflate. Thus, Islava actually teaches away from applicant's claimed construction¹.

¹ Islava states in column 4, lines 21-24, that "If a single latitudinal weld 40 were provided to extend across the entire width of the splint, the perforation may also extend through the entire width of the splint 10." However, there is no disclosure that any such perforated weld would be "continuous", as claimed by applicant, or that any such perforated weld could be used to completely remove one section of the splint from another section. On the contrary, as discussed above, the patent emphasizes the importance of keeping the un-welded center portion of the splint intact so that it can function as a hinge. Further, as also discussed, a continuous weld completely across the splint would create a non-functional product.

For all of these reasons, applicant's invention as defined by amended claim 1 would not have been obvious in view of Oguri et al. and Islava.

The Poole et al. patent shows a pressure garment having zipper connections 16 which "are designed to be opened to allow medical personnel to gain access to certain arteries located for example at 38." (Column 3, lines 14-18.) Further, Poole et al. state that "The zipper connections 16 allow for easy replacement of damaged modular components, without having to scrap the entire garment." (Column 3, lines 22-25.) The zipper connections allow for connection and re-connection, which is very different from applicant's arrangement where one sleeve portion is permanently and irreversibly removed from the other sleeve portion when the sleeve is torn along the perforations. Nor would it be appropriate to use applicant's claimed arrangement in Poole et al., since the express purpose of using zippers is to permit re-connection of the parts. Moreover, the present invention does not involve the cost of a zipper and its additional manufacturing cost associated with attachment to the compression sleeve.

Accordingly, claim 1 and claims 2, 5, 6 and 11-14 depending therefrom are not made obvious by the combination of Oguri et al., Islava and Poole et al.

Claim 18 is amended to state the step of "completely" removing the first portion of the sleeve from the second portion of the sleeve "by tearing the sleeve along perforations in the sleeve." This step is not taught or disclosed by the combination of Oguri et al., Islava and Poole et al. for the same reasons given above in regard to claim 1. Thus, claim 18 and claims 19 and 20 depending therefrom are submitted to be allowable.

In view of the foregoing, applicant requests that the rejection of claims 1, 5-7, 11, 13, 14, and 18-20 under 35 USC §103 be withdrawn.

Claims 3 and 4 are rejected as unpatentable over the references applied to claim 1 and further in view of Rotta (3,862,629). The Oguri et al., Poole et al. and Islava patents are discussed above. Rotta discloses a device comprising a series of inflatable chambers constructed as modular units and valves which can be plugged together to make a series of any desired length. The units are connected by inserting valve nipples 30, 32 into chamber openings 34 and, presumably, disconnected by reversing the process. (See column 5, lines 1-10.)

Claims 3 and 4 depend from claim 1 which, as noted above, is directed to the non-obvious feature of a sleeve having perforations extending continuously across the sleeve from adjacent one boundary edge of the sleeve to adjacent an opposite boundary edge of the sleeve, the first and second portions of the sleeve being located on opposite sides of the perforations whereby the sleeve may be torn along the perforations to completely remove the first portion of the sleeve from the second portion of the sleeve. This feature is neither disclosed nor suggested by the claim1 references or Rotta. The Oguri et al., Poole et al. and Rotta patents are directed to devices having components (upper and lower suit parts in Oguri et al., modular sections in Poole et al., and modular units in Rotta) which can be connected, disconnected and reconnected in different configurations. In this context, it is important that the connections between the components be of the type that can be used more than once. In sharp contrast, claim 1 is directed to a sleeve having perforations which allow the sleeve to be torn to effect complete removal of the first part of the sleeve from the second part of the sleeve. Once the sleeve is torn, the two parts cannot be reattached, i.e., the removal process is irreversible. Thus, applicant's claimed design is not only entirely different in structure from the connections in Oguri et al., Poole et al. and Rotta, it provides an entirely different result, namely, re-connection in the case of Oguri et al., Poole et al. and Rotta versus no re-connection in applicant's claimed design. It would be entirely inappropriate and counter to the purpose of the patented devices to include "tear away" connections between the components.

For these reasons, claim 1 and claims 3 and 4 depending therefrom are not obvious in view of the claim 1 references and Rotta.

Claim 7 is rejected as unpatentable over Oguri et al. Claim 7 depends (indirectly) from claim 1 and thus includes the "tear away" feature in amended claim 1. For the reasons given above, Oguri et al. neither disclose nor suggest this feature. Accordingly, claim 7 is submitted to be patentable for at least this reason.

Claims 8-10 are rejected as unpatentable over Oguri et al. and Dye (5,795,312). These claims incorporate the subject matter of claim 1 and are a submitted to be allowable for at least the same reasons as claim 1. In this regard, Dye discloses a compression sleeve having thigh and calf portions, but these portions are not removable from one another. Accordingly, Dye is not relevant to the "tear away" feature of claim 1.

Claims 1, 5-7, 11, 13-20, 22, and 24-26 are rejected as unpatentable over Dye (5,795,312) in view of Islava, Oguri et al. and Arkans (6,062,244). The Examiner properly admits that Dye '312 does not teach removing the thigh portion from knee portion. Dye '312 is currently owned by the assignee of the present invention, and Dye '312 represents a much earlier idea in the area of compression therapy.

The Examiner states that it would have been obvious in view of Islava to modify Dye's compressive sleeve to include perforations so that different sections of the sleeve can be disassembled and used independently. In support of this assertion, the examiner quotes from Islava at column 4, lines 53-55 stating that "detaching one portion 50 from another portion 60 also enables each portion to form a structure independently from the other." However, as noted above in regard to claim 1, this quote must be considered in the context of the entire paragraph which makes it clear that the detachment referred to is only a **partial** detachment. The center portion 29 of the splint remains intact so that it can function as a hinge between the two partially detached splint portions 50, 60. Therefore, as discussed earlier, when considered as a whole Islava would not lead one of ordinary skill to applicant's claimed invention in which perforations extend **continuously** across the sleeve from adjacent one boundary edge of the sleeve to adjacent an opposite boundary edge of the sleeve to allow for the **complete** removal of one part of a compression sleeve from another part of the sleeve.

Completely removing one portion of Dye's sleeve as suggested by the examiner would not be obvious for the additional reason that any such removal would render Dye's sleeve inoperable for its intended purpose. It will be noted in this regard that Dye's sleeve is connected via a connector 48 to a controller (not shown) for supplying pressurized air to the sleeve (see column 3, lines 33-35). The controller operates in conventional fashion to sequentially inflate the various sections of the sleeve (column 4, line 65 to column 5, line 10). Removing a portion of Dye's sleeve by tearing along a line of perforations, as suggested by the examiner, would require disconnection of the fluid conduit associated with the removed portion (e.g., conduit 46d). The skilled person would know that any such disconnection would be immediately sensed by the controller and trigger an alarm program resulting in the stoppage of further flow of pressurized fluid

to the sleeve. The fact that removal of a portion of Dye's sleeve would render the device inoperable is strong evidence of non-obviousness (MPEP 2143.01(V)).

Similarly, the patent to Oguri et al. fails to teach applicant's claimed invention. As discussed above in regard to claim 1, Oguri et al. teaches only the use of connectors which can be connected and re-connected. Thus, this reference actually teaches away from the use of applicant's continuous perforations which, once torn, cannot be re-connected.

Arkans '244 is currently owned by the assignee of the present invention. Like Dye '312, Arkans '244 is an earlier development in the area of compression therapy. In Fig. 1, Arkans discloses a prior art compression device 10 comprising a foot cuff 36 and a calf cuff 38 connected by tubing to a controller unit 20. The tubing includes two tubing sets 30, 32 connected to one another by connectors 28, 29. The patent further teaches replacing the prior art connectors of Fig. 1 with a new connector unit 40 which includes mating upstream and downstream connectors 42, 44. The upstream connector 42 is connected to the controller by tubing as shown in Fig. 1 (column 5, lines 9-12), and the downstream connector 44 is connected to respective cuffs 36, 38 by downstream tubes 50a, 50b. Preferably, shut-off valves 60a, 60b are positioned within the upstream connector 42 and block fluid flow from the controller when the connectors are disconnected (column 5, lines 44-49). The downstream connector 44 is configured to open the shut-off valves when the connectors are re-connected to permit flow to the cuffs (column 5, lines 50-63). Arkans is completely devoid of any teaching of a perforation to tear a first sleeve portion from a second sleeve portion. Accordingly, this reference cannot make applicant's claimed invention obvious.

The examiner also relies on Arkans '244 to reject claim 15 which adds the element of a valve connector that fluidly communicates with both a pressurized fluid source and the air chambers of the sleeve via a tubular pathway to facilitate inflation of the chambers. As amended, claim 15 defines the tubular pathway as comprising first tubing extending from the valve connector and fluidly connecting to the first expandable chamber, second tubing extending from the valve connector and fluidly connecting to the second expandable chamber, and third tubing extending from the valve connector and fluidly connecting to the third expandable chamber. Amended claim 15 further states that

the first tubing of the tubular pathway is removable from the valve connector when the thigh portion of the sleeve is removed from the calf portion of the sleeve, and that the second tubing and third tubing remain attached to the valve connector when the thigh portion is removed from the calf portion. This feature is neither shown nor suggested by Arkans. In Arkans, the two downstream tubes 50a, 50b supplying fluid to the cuffs 36, 38 remain attached to the downstream connector 44 at all times. There is no disclosure or suggestion that one tube can be removed from the connector while the other tube remains attached to the connector.

For this additional reason, claim 15 and claims 16-17 depending therefrom are believed to be allowable.

In view of the foregoing, applicant respectfully requests allowance of independent claims 1, 15, 18, and 25 and dependent claims 3-14 and claim 28 as depending from an allowable claim 1, and dependent claims 16-17 as depending from an allowable claim 15, and dependent claims 19-20 as depending from an allowable claim 18, and dependent claim 26 depending from an allowable claim 25.

Claims 1, 11, 12, 28 and 29 are rejected as unpatentable over Dye '312 in view of Islava, Oguri et al. and Mitchell (2,638,915). Dye, Islava and Oguri et al. are discussed above. Mitchell discloses a self-sealing hydraulic fluid coupling that seals against flow when the components of the coupling are disconnected. None of these references shows or suggests the tear-away feature of claim 1. Accordingly, claim 1 and dependent claims 11, 12 and 28 are believed to be allowable over these references for at least the reasons explained above in regard to claim 1.

Claim 29 is further amended to include an additional connector feature in which the connector comprises a fluid port and a valve for **partially** closing the fluid port when the first tubing leading to the tear-away portion of the sleeve is removed from the connector. Because the valve only partially closes, fluid is able to continue to flow from the fluid port and inflation and deflation of the remaining portion of the sleeve by the pressurized fluid source is able to continue without interruption. As noted previously, a compression sleeve of this invention is used for vascular therapy. In such use, the chambers of the sleeve are inflated and deflated by a pressurized air source, i.e., a controller. Fluid pressure feedback information to the controller is necessary to achieve

proper operation. If a portion of the sleeve is removed, this feedback is interrupted and would normally cause the controller to discontinue operation. However, when the sleeve is equipped with the valve connector of claim 29, pressurized fluid continues to flow through the fluid port even after a portion of the sleeve is torn away and the associated tubing is disconnected from the fluid port of the connector. This continued flow simulates the flow characteristics prior to such disconnection so that the controller continues to operate as if the disconnection had not occurred. (For further details of this valve connection, see page 8, lines 12, lines 6-15 of the present application and Application Ser. No. 10/784,639, published August 25, 2005 as Publication No. 2005/01842645, incorporated by reference in this application).

The additional connector valve feature of claim 29 is not shown or suggested by Dye, Islava, Oguri et al. or Mitchell. Dye and Islava fail to show valve connectors of any type. Oguri et al. disclose the use of stoppers 18 (Fig. 6) for **preventing** the flow of air from the lower part of the suit after the upper part is disconnected (column 6, lines 21-27). Mitchell shows a hydraulic system for a tractor-drawn apparatus, such as a farming implement. The system includes a pump 26, two hydraulic motors 32, 36, and fluid conduits 12, 14, 16, 18 connected by the coupling unit 10. The coupling unit comprises a block 44 having two bores 48 connected by a bypass passage 48, and two coupling sections 59, 60 associated with each of the two bores. The coupling sections are used for connecting a first pair of conduit sections 12, 14 to one another and a second pair of conduit sections 16, 18 to one another. In the event the implement on which the first motor 30 is mounted is disconnected from the tractor and the first pair of conduit sections 12, 14 is subjected to a pulling force, both conduit sections disconnect from the coupling unit (column 8, lines 22-28). Upon disconnection, valve members 98, 140 close to seal the coupling sections 59, 60 and the detached conduit sections 12, 14 (column 8, lines 60-64). There is **no flow** through the closed valve members 98 after disconnection.

For this additional reason, claim 29 as amended is believed to be allowable.

New claim 30

New claim 30 depends from claim 29 and states that the valve of the connector is movable when the first tubing is removed from the connector to reduce fluid flow from the pressurized fluid source through the fluid port of the connector to a level approximating flow to the first expandable chamber prior to removal of the first portion of the sleeve from the second portion of the sleeve. As discussed above, this feature is advantageous because it maintains continuity with the pressurized fluid source so that vascular therapy can continue without interruption after the first portion of the sleeve is removed by tearing along the perforations. (See page 12, lines 6-15 of the present application.) There is no disclosure or suggestion of this feature in the cited prior art.

Accordingly, for this additional reason, applicant requests the allowance of claim 30.

CONCLUSION

The Commissioner is hereby authorized to charge any fees due for additional claims to Deposit Account No. 19-0254. The Commissioner is also authorized to charge any additional fees due or credit any overpayment to Deposit Account No. 19-0254. The Applicant requests an extension of time under 37 CFR 1.136(a) for (2) months.. In view of the foregoing, favorable consideration and allowance of this application is requested.

Respectfully submitted,



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